II.C.4.

Documents in the administrative record confirm that in designing cigarettes to meet "consumer demands," the cigarette manufacturers carefully take into account consumers' pharmacological need for nicotine. One example is Project Wheat. As discussed above in section II.C.3.c.ii., BATCO conducted Project Wheat in the mid-1970's to determine smokers' "Inner Need" for nicotine.[802] BATCO undertook this research for the express purpose of improving its ability to meet consumer demands. As the BATCO researchers stated, Project Wheat was "*seen as a part of a general approach to the problem of designing cigarettes of increased consumer acceptance*" because "*[i]n considering which product features are important in terms of consumer acceptance, the nicotine delivery is one of the more obvious candidates.*" [803]

Project Wheat found that no cigarettes then on the market provided the "low tar and medium nicotine deliveries" sought by smokers who had an average "Inner Need" for nicotine, but "an above average concern for health."[804] According to a "model of the market" developed in Project Wheat, over 40% of smokers wanted cigarettes with a higher ratio of nicotine to tar than was then available.[805] Shortly thereafter, ultra-low-tar cigarettes made with nicotine-rich tobacco blends were introduced into the market, including a Brown & Williamson cigarette called Barclay. *See* section II.C.4.a.ii., above.

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[802] Wood DJ, Wilkes EB (BATCO), *Project Wheat - Part 1: Cluster Profiles of U.K. Male Smokers and Their General Smoking Habits* (Jul. 10, 1975), at 1. *See* AR (Vol. 20 Ref. 204-1).

[803] *Id.* at 1, 3 (emphasis added).

[804] Wood DJ (BATCO), *Project Wheat - Part 2: U.K. Male Smokers: Their Reactions to Cigarettes of Different Nicotine Delivery as Influenced by Inner Need* (Jan. 30, 1976), at 2. *See* AR (Vol. 20 Ref. 204-2).

[805] BATCO Group R&D Conference on Smoking Behaviour at Southampton, England (Oct. 11-12, 1976), at BW-W2-02308. *See* AR (Vol. 178 Ref. 2074).

The process of "consumer preference testing," which is described in the comments of the cigarette manufacturers, is one of the ways the manufacturers refine nicotine deliveries. In its comments, Brown & Williamson explains that it asks consumers to rate prototype cigarettes to determine if its tobacco blends produce "satisfaction," "strength," and other desirable attributes to consumers. According to Brown & Williamson, "satisfaction," as used in consumer preference testing, "reflects the consumer's total reaction to the total smoking experience delivered by the cigarettes."[806] If consumer testing shows that a Brown & Williamson cigarette produces insufficient satisfaction, Brown & Williamson says its product developers will "adjust product recipes and designs to improve or maintain product preference."[807]

In reality, however, Brown & Williamson knows that nicotine's pharmacological effects play the primary role in consumer "satisfaction." For instance, in 1983, BATCO researchers reported their "basic assumption" that "*nicotine, . . . is almost certainly the key smoke component for satisfaction.*"[808] Likewise, in a 1984 conference, the BATCO researchers reported that "*'satisfaction' must be related to nicotine.* Many people believe it [is] a 'whole body response' and *involves the action of nicotine in the brain.*"[809] Thus, Brown & Williamson understands that reports of inadequate satisfaction in consumer preference testing can signal a need to enhance nicotine deliveries.

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[806] Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 8. *See* AR (Vol. 529 Ref. 104).

[807] *Id.* at 9.

[808] Minutes of BATCO Research Conference at Rio de Janeiro (Aug. 22-26, 1983), at 10 (emphasis added). *See* AR (Vol. 22 Ref. 287-5).

[809] BATCO, *Conference Outline* (Jun. 6-8, 1984), at BW-W2-01977 (citation omitted) (emphasis added). *See* AR (Vol. 22 Ref. 287-6).

The statements of William Farone, the former Philip Morris director of applied research, and Ian Uydess, the former Philip Morris scientist, make precisely this point. They confirm that product developers for the cigarette manufacturers do in fact adjust nicotine levels during consumer testing. According to Farone:

> *This concept of nicotine delivery being essential to consumer satisfaction was common knowledge within Philip Morris and the rest of the industry. When consumer testing indicated that a product was lacking in "impact" or some similar descriptor that could be associated with nicotine, experienced market researchers and product developers would compensate by increasing nicotine levels . . . .*[810]

Similarly, Ian Uydess states:

> In the case of nicotine, specific levels of nicotine would be targeted in the test products (test 'articles') in a range that extended from 'ultra-low' (or even zero) nicotine deliveries, to deliveries equal to, or slightly above that found in some of their own (or a competitor's) 'full-flavor' or 'full-bodied' products. This was done to examine how the smoker would react to various nicotine levels as a predictor of how well these products might do in the market with specific regard to: "not enough nicotine", "an acceptable level of nicotine", or "too much nicotine."[811]

Thus, the Agency concludes that the manufacturers' explanation for their actions does not withstand scrutiny. Overwhelming evidence establishes that smokers seek the pharmacological effects of nicotine from cigarettes. *See* section II.A. and II.B., above. Overwhelming evidence also establishes that the manufacturers know that. *See* section II.C.2., above. Manufacturers that design their products to meet consumer demands that

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[810] Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 8 (emphasis added). *See* AR (Vol. 638 Ref. 2).

[811] Declaration of Uydess IL (Feb. 29, 1996), at 11. *See* AR (Vol. 638 Ref. 1).

they know are pharmacological in nature are necessarily engaged in designing products to provide pharmacological effects.

In sum, the evidence discussed in this section discloses that the manufacturers use several methods to control and manipulate nicotine deliveries in commercial cigarettes. These design features include: (1) the use of various tobacco blends with varying nicotine levels; (2) filter ventilation and related technologies that selectively remove more tar than nicotine and allow smokers to obtain more nicotine than the measured FTC yields; and (3) the use of ammonia technologies that increase the delivery of "free" nicotine. In addition, the evidence shows that the manufacturers control nicotine levels in virtually all aspects of cigarette manufacture, thereby ensuring that smokers receive a consistent nicotine delivery in each cigarette. Combined with the evidence regarding product research and development in section II.C.3., this evidence shows that the manufacturers "design" cigarettes to provide a consistent, pharmacologically active dose of nicotine to smokers, thereby establishing that cigarettes are "intended" to affect the structure and function of the body.

5. Conclusion

The Agency's role in determining intended use through the statements, research, and actions of the manufacturer is to be a fact finder. In this case, after careful consideration of the evidence and the comments, the Agency finds that the evidence of cigarette manufacturers' statements, research, and actions demonstrates that cigarettes are intended to cause significant pharmacological effects in smokers. The Agency makes this finding for three principal reasons.

II.C.5.

First, as described in section II.C.2., above, the evidence shows that the cigarette manufacturers are aware of and have exhaustively studied the pharmacological effects and uses of nicotine. In the case of Philip Morris, RJR, and Brown & Williamson, the manufacturers conducted extensive in-house research on the pharmacological effects and uses of nicotine. Their researchers and officials repeatedly expressed the view that nicotine causes pharmacological effects, that consumers smoke cigarettes to obtain these effects, and that cigarettes are delivery devices for nicotine. The evidence further shows that the cigarette manufacturers as a group funded extensive research into nicotine pharmacology through the Council for Tobacco Research. This evidence establishes that the manufacturers "have in mind" that cigarettes will be used for the particular purpose of delivering the pharmacological effects of nicotine to smokers.

Second, the evidence in sections II.C.3. and II.C.4. shows that the cigarette manufacturers "design" cigarettes to have pharmacological effects. This evidence reveals that the manufacturers have conducted extensive product research and development to identify pharmacologically active doses of nicotine and to optimize the delivery of nicotine to smokers and that company researchers repeatedly recommended the development of cigarettes that maintain adequate nicotine deliveries.

This evidence also shows that the cigarette manufacturers carefully control and manipulate the nicotine delivery of their commercially marketed cigarettes to provide smokers with a pharmacologically active dose of nicotine. Among other practices, the manufacturers use high-nicotine blends that increase nicotine deliveries in their lowest-tar products; rely on filtration and ventilation technologies that selectively remove more tar than nicotine; add ammonia compounds that increase the delivery of "free" nicotine; and

carefully control the nicotine level in all cigarettes. Through the use of these practices, the cigarette manufacturers are able to deliver sufficient nicotine to satisfy consumers. An inevitable consequence of these practices is to keep consumers smoking by sustaining their addiction.

Third, the manufacturers have been unable to provide a convincing explanation that refutes either the evidence showing that they have in mind the pharmacological effects and uses of cigarettes or the evidence showing that they have designed cigarettes to provide these effects. This failure is significant because the manufacturers alone have access to the company documents and other information that would provide a complete explanation of their knowledge and design practices. The absence of a credible counter-explanation by the persons best situated to explain the evidence before the Agency adds additional support for the Agency's findings.

Under the legal standards described in section II.C.1., above, the evidence that the manufacturers (1) "have in mind" that cigarettes will be used for pharmacological purposes and (2) "design" cigarettes to deliver a pharmacologically active dose of nicotine each provides an independent basis for establishing intended use. Taken together, the two categories of evidence are consistent with each other and mutually reinforcing. Taken as a whole, therefore, the evidence from the statements, research, and actions of the manufacturers amply supports the finding that the effects of cigarettes on the structure and function of the body are "intended" by the cigarette manufacturers.

6. Response to Comments

a. Comments on Statements and Research on Nicotine's Drug Effects

i. Comments on Specific Philip Morris Statements and Research Projects. In July 1995, a large number of Philip Morris internal documents reflecting over a decade of its research on smoking motivation were published in the *Congressional Record.* A smaller number of documents from Philip Morris became available as a result of a lawsuit brought against Philip Morris by a smoker.[812] In its Jurisdictional Analysis, FDA reproduced statements from those documents as evidence that company officials believed that consumers use cigarettes to obtain the pharmacological effects of nicotine.

A comment submitted by Philip Morris argues that the documents do not provide such evidence because FDA allegedly mischaracterized or took out of context some of the quotes from the documents. Philip Morris argues that: (1) other statements in the documents show that Philip Morris researchers were actually uncertain why people smoke; (2) in addition to studies on the pharmacological motivations for smoking, Philip Morris conducted studies on other motives for smoking, demonstrating that Philip Morris did not believe that pharmacological motives for smoking were primary; (3) FDA omitted passages from the documents that would have cast them in a different light; and (4) some of the statements cited by FDA were actually only hypotheses of Philip Morris researchers, or the hypotheses of outside researchers, which were not ultimately supported by the results of their studies.

[812] *Cipollone v. Liggett Group Inc.*, No. 83-2864 (D.N.J. dismissed Nov. 3, 1992).

II.C.6.

FDA has reviewed all of the publicly available documents written by Philip Morris officials. The Agency has concluded that, both individually and as a whole, they demonstrate that Philip Morris conducted extensive, sophisticated research on the pharmacological effects of nicotine in cigarettes and the pharmacological motives for smoking, and that officials responsible for research and development at all levels of the company expressed consistent beliefs throughout the period covered by the documents that the pharmacological effects of nicotine were the primary reason people smoke. The documents also demonstrate that these beliefs, and the data supporting them, were held by and communicated to company executives, including the board of directors. Below, FDA addresses each of Philip Morris' arguments, with examples from individual documents claimed by Philip Morris to have been mischaracterized. In every case, the documents speak for themselves.

1. Philip Morris argues that it conducted studies on other motives for smoking, demonstrating that Philip Morris did not believe that pharmacological motives for smoking were primary. Philip Morris cites a single document from 1970 for this premise.

FDA has reviewed the studies on smoking motivation referred to in the publicly available Philip Morris documents. The relative importance Philip Morris placed on pharmacological motives for smoking compared to other motives is clear from these studies. The vast majority of the company's studies were conducted to assess the pharmacological effects of, and motives for, smoking. A small minority of the studies were intended to assess other reasons for smoking. Indeed, the research documents show that Philip Morris' focus on the pharmacological effects of nicotine increased over time.

By the early 1980's, when the large collection of documents made public by Congress end, Philip Morris' research on smoking motivation was overwhelmingly dominated by research on the pharmacological effects of nicotine. A 1980 report, for instance, describes fifteen major studies—eleven of which examined various aspects of nicotine's pharmacological effects on smokers and on dose-regulating behavior by smokers.[813] The nicotine-related studies included:

(1) Studies on the effects of cigarettes and nicotine on electrical and chemical activity in the human brain. The objectives of this program are described as follows:

> It is our belief that the reinforcing properties of cigarette smoking are directly relatable to the effects that smoking has on electrical and chemical events within the central nervous system. Therefore, the goals of the electrophysiology program are to: (I) Determine how cigarette smoking affects the electrical activity of the brain, and (II) Identify, as far as possible, the neural elements which mediate cigarette smoking's reinforcing actions.[814]

(2) Studies on rats demonstrating that nicotine is "reinforcing" (causes animals to "self-administ[er]" nicotine, i.e., seek repeated doses), tests positive in drug discrimination tests which can predict whether a substance has mood-altering effects in humans, and acts centrally in the brain. The objectives of this program include "(I) To develop a better understanding of the behavioral pharmacological actions of nicotine, particularly the action which reinforces smoking behavior."[815]

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[813] Dunn WL (Philip Morris Inc.), *Plans and Objectives–1981* (Nov. 26, 1980), in 141 Cong. Rec. H7681–7683 (daily ed. Jul. 25, 1995). *See* AR (Vol. 14 Ref. 175a).

[814] *Id.* at H7681.

[815] *Id.* at H7682.

(3) Studies on the level of nicotine in saliva over time, and on the correlation of salivary nicotine levels to blood nicotine levels, to answer the question, "Does a low systemic level of nicotine trigger the smoking response?"[816]

Philip Morris provides no additional or later documents that would suggest that these studies are not representative. Thus, the extensive and sustained investigation into nicotine pharmacology reflected in Philip Morris' documents demonstrates that its researchers believed that the pharmacological effects of nicotine were the primary reason for smoking. Moreover, as detailed in section II.C.2.a.iii., above, a 1992 Philip Morris document shows that the views expressed by Philip Morris officials in the 1970's and 1980's are still held by Philip Morris employees.[817]

Moreover, even if Philip Morris had significantly researched other motives for smoking, this could not render Philip Morris' research into the pharmacological motives for smoking irrelevant. Neither FDA nor the courts have suggested that a product with pharmacological uses must not have any other uses if it is to be regulated as a drug or device. When it has been established that a manufacturer intends that its product be used for a pharmacological purpose, FDA's jurisdiction is not defeated by a showing that the

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[816] *Id.* at H7682.

See also Dunn WL (Philip Morris Inc.), *Plans and Objectives–1979* (Dec. 6, 1978) ("All of the effort of the Behavioral Research Laboratory is aimed at achieving this objective: To understand the psychological reward the smoker gets from smoking, to understand the psychophysiology underlying this reward, and to relate this reward to the constituents in smoke"), in 141 Cong. Rec. H7668–7670 (daily ed. Jul. 25, 1995). *See* AR (Vol. 14 Ref. 175a).

Dunn WL (Philip Morris Inc.), *Plans and Objectives–1980* (Jan. 7, 1980), in 141 Cong. Rec. H7670–7672 (daily ed. Jul. 25, 1995). *See* AR (Vol. 14 Ref. 175a).

[817] Philip Morris Inc., Draft Report Regarding a Proposal for a "Safer" Cigarette, Code-named *Table*. *See* AR (Vol. 531 Ref. 122).